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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,550	03/17/2004	Patrick Fogarty	TOSK-007CIPCON	5663

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EXAMINER	
SGAGIAS, MAGDALENE K	
ART UNIT	**PAPER NUMBER**
1632	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,550	FOGARTY, PATRICK	
	Examiner	**Art Unit**	
	MAGDALENE K. SGAGIAS	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 03 March 2008.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 11,13-15,27,31 and 39-42 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) 11, 13-15, 27, 31, 39-42 is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/3/08 has been entered.

Claims 11, 13-15, 27, 31, 39-42 are pending and under consideration. The amendment has been entered. Claims 1-10, 12, 16-26, 28-38 are canceled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 13-15, 27, 31, 39-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Fogarty et al. (U.S. Patent 6,291,243 B1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Fogarty et al. teach and claim a method of inserting an exogenous nucleic acid into a non- insect target cell genome using a P element derived vector (claim 12). The P element derived vector comprises a pair of P element transposase recognition sites flanking at least two non- insect cell transcriptionally active expression modules each comprising a coding sequence and a promoter (claim 1). The P element vector taught by Fogarty et al. further comprises that said transposase recognition sites are 31 base pair inverted repeats (claim 6). Fogarty et al. teaches that the P element vector comprises an inter P feet domain that the inter P feet domain of the vectors, i.e. that domain or region of the vector located or positioned between the P feet which includes the at least two transcriptionally active genes and the exogenous nucleic acid, when present, may vary greatly in size (column 4, lines 1-11). Typically, the size of this inter P feet domain (i.e. P feet flanked domain) is at least about 50 bp in length, usually at least about 1000 bp in length and more usually <u>at least about 2000 bp in length</u>, where the length of this domain may be as long as 150,000 bp or longer, but generally does not exceed about 20,000 bp in length and more usually does not exceed about 10,000 bp in length (col. 4 lines 1-11). This teaching by Fogarty anticipates that a single transcriptionally active gene is separated from a P element transposase domain by a distance of about 1000bp. The claims in the 243' patent are drawn to a method of using a P element vector that comprises at least two non-insect cell genes flanked by a pair of P element transposase recognition sites, however Fogarty et al. in their specification teach that a single gene can be flanked by said transposase recognition sites (col. 5 lines 5-9). Fogarty et al. explicitly states that " Vectors of this embodiment that include a single transcriptionally active gene may be prepared and used as described below, where the following description is provided in terms of vectors that include at least two transcriptionally active genes." (col. 5 lines 5-9). Fogarty et al. further teach that the P element vector can be used to insert exogenous or endogenous nucleic acids into the genomes of mammalian cells

including rat and murine (col. 5 lines 42-59). Fogarty et al. further teach that a second vector comprising a transposase domain into said cell can be delivered using the claimed method (claim 14). With regard to the claimed mouse made by the claimed method, the prior art is enabling to the extent that a transgenic mouse is created using the claimed method and the method disclosed in the 243' patent. Fogarty teaches that the claimed method, which is a transformation method, can be used for the creation of transgenic animals, including rodents (col. 1 lines 16-28).

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. I*n re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972) and In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34(CCPA 1977)).

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

“Products of identical chemical composition can not have mutually exclusive properties.” A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the

identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Applicant is referred to MPEP 2112 for further discussion on inherency.

Thus Fogarty et al. clearly anticipate the claimed method.

Applicants argue the claims require the presence of a p-feet flanked domain of at least 2000 bp comprising a transcriptionally active gene that is less than 1000 bp from one of the p-feet. It is not seen where this element is taught in the cited '243 patent.

This is not found persuasive because in the '243 patent it is cited domain that the inter P feet domain of the vectors, i.e. that domain or region of the vector located or positioned between the P feet which includes the at least two transcriptionally active genes and the exogenous nucleic acid, when present, may vary greatly in size (column 4, lines 1-11). Typically, the size of this inter P feet domain (i.e. P feet flanked domain) is at least about 50 bp in length, usually at least about 1000 bp in length and more usually at least about 2000 bp in length, where the length of this domain may be as long as 150,000 bp or longer, but generally does not exceed about 20,000 bp in length and more usually does not exceed about 10,000 bp in length (col. 4 lines 1-11). Therefore, '243 patent anticipates a transcriptionally active gene that is less than 100bp from one of the p-feet.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 13-15, 27, 31, 39-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

While the art teaches integration of a P-element vector the size of this inter P feet domain (i.e. P feet flanked domain) is at least about 50 bp in length, usually at least about 1000 bp in length and more usually at least about 2000 bp in length, where the length of this domain may be as long as 150,000 bp or longer, but generally does not exceed about 20,000 bp in length and more usually does not exceed about 10,000 bp in length in a mouse the specification does not teach said P-element integration into a mouse.

Claims are drawn to a method of inserting an exogenous nucleic acid into the genome of a mouse or rat, said method comprising: introducing into said mouse or rat a P-element derived vector comprising said exogenous nucleic acid under conditions sufficient for transposition to occur, wherein said vector comprises a pair of P-element transposase recognized insertion sequences flanking a P-feet flanked domain of at least about 2000 bp in length wherein said P-feet flanked domain comprises a heterologous promoter and a single transcriptionally active gene that comprises said exogenous nucleic acid, wherein said single transcriptionally active gene is separated from one of said P-element transposase recognized insertion sequences by a distance of about 1,000 bp or less, so that said exogenous nucleic acid is inserted into said genome.

The working examples provided by the specification teach that male mice were co-injected with a canonical P-element C3.1 vector and transposase vector via system tail vein injection (p 18 lines 6-14). The specification continues to teach that, "Depending on the structure of the vector itself, i.e., whether or not the vector includes a region encoding a product having P

element transposase activity, the method may further include introducing a second vector into the animal which encodes the requisite transposase activity" (pg. 11 lines 11-15). The specification teaches that co-injection of said vectors resulted in successful integration of the C3.1 vector in a dose-dependent manner into the genomes of said mice that was determined by PCR analysis in testis, liver, spleen, heart, lung, brain, and intestine tissue (pg. 18 lines 16-23 bridge pg. 19 lines 5-17). The specification continues to teach that said vectors were heritable when transgenic mice were bred, resulting in up to 71% of offspring being transgenic (pg. 19 lines 23-24 bridge pg. 20 lines 1-6). However, the guidance provided by the instant specification fails to correlate the integration of the C3.1 P-element vector into the tissues of mice via tail vein injection into the insertion of a P-element vector comprises a pair of P-element transposase recognized insertion sequences flanking a P-feet flanked domain of at least about 2000 bp in length wherein said P-feet flanked domain comprises a heterologous promoter and a single transcriptionally active gene that comprises said exogenous nucleic acid, wherein said single transcriptionally active gene is separated from one of said P-element transposase recognized insertion sequences by a distance of about 1,000 bp or less, so that said exogenous nucleic acid is inserted into said genome. Thus, as enablement requires the specification to teach how to make and use the claimed invention, the specification fails to enable the claimed methods for inserting the claimed P-element derived vector into a rat or a mouse. It would have required undue experimentation to make and use the claimed invention without a reasonable expectation of success.

At the time of the instant invention the art teaches that creating a transgenic mouse or rat animal, via a P-element transposition in the field of transgenesis is unpredictable. **Castro et al** (Genetica, 121: 107-118, 2004) note the molecular mechanisms that control P element transposition and determine its tissue specificity remain incompletely understood, although

much information has been compiled about the element in the last decade (abstract). **Plasterk et al**, (TIG, 15(8): 326-332, 1999) note transgenic technology is currently applied to several animal species of agricultural or medical importance, such as fish, cattle, mosquitos and parasitic worms (abstract). However, the repertoire of genetic tools used for molecular analyses of mice and Drosophila is not always applicable to other species. For example, while retroviral enhancer-trap experiments in mice can be based on embryonic stem (ES) cell technology, this is not currently an option with other animals. Similarly, the germline transformation of Drosophila depends on the use of the P-element transposon, which does not jump in other genera (abstract). This article analyses the main characteristics of Tc1/mariner transposable elements, examines some of the factors that have contributed to their evolutionary success, and describes their potential, as well as their limitations, for transgenesis and insertional mutagenesis in diverse animals (abstract).

Whereas the nature of the invention teaches is a method of creating transgenic mouse or rat animal, the art teaches that the field of transgenesis is unpredictable. The art teaches that transgenic mouse lines are generated by microinjection of the linear DNA of interest into the nucleus of an oocyte or transfected into embryonic stem (ES) cells, which then randomly integrates into the genome (Ristevski, Molecular Biotechnology, Vol. 29, 2005, pg. 159 col. 1 parag. 2 lines 1-5). Currently only mouse ES cells have been established that result in a transgenic animal (Smith, 2002, J. of Biotechnology, Vol. 99, pg. 3 col. 1, parag. 4 lines 1-3). With regard to transgene integration the art teaches that the site of integration is uncontrolled and yet is critical due to the possibility of integration into a silent locus. Random integration may occur, resulting in the insertional inactivation (insertional mutagenesis) of a gene at the site of integration, resulting in a loss of function that may be mistakenly attributed to over expression of the transgene (Ristevski, pg. 159 col. 1 parag. 2 lines 5-14). Further, insertional mutagenesis of

a gene may not be immediately apparent if a recessive gene has been inactivated, as phenotypic abnormalities will not be evident until homozygous transgenic lines have been established (Ristevski, pg. 159 col. 1 parag. 2 lines 14-19). The site of integration may also result in altered tissue specificity, although the promoter used behaves differently at its normal chromosomal localization, with neighboring regulatory elements potentially influencing the transcriptional activity of the transgene (Ristevski, pg. 159 col. 1 parag. 3 lines 1-7). This is known as chromosomal position effects, where host sequences surrounding the site of transgene integration can alter the expected expression pattern, turning it ectopic or not detectable (Montoliu, 2002, Cloning and Stem Cells, Vol. 4, pg 39, col. 1). With regard to copy number the art teaches that controlling the transgene copy number (usually integration is a singular event with multiple copies integrated in tandem) is also problematic in the generation of transgenic animals (Ristevski, pg. 159 col. 1 parag. 3 lines 7-11). A high tandem copy number results in a gene silencing effect, and further, is undesirable if the effect of a gene dosage is being addressed, as multiple copies will not recapitulate relevant levels of expression (Ristevski, pg. 159 col. 1 parag. 3 lines 11-14 bridge col. 2 parag. 1). With regard to transgene expression, the art teaches bluntly that, “many transgenes work poorly” (Houdebine, 2002, J. of Biotechnology, Vol. 98, pg. 150, col. 1 parag. 4 line 1). Transgene expression is often very low or not specific of the promoter added in the gene construct, and are generally attributed to position effects in chromatin as discussed above (Houdebine, pg. 150, col. 1 parag. 4 lines 1-5). The art continues to teach that a transgene is generally poorly expressed when it contains a cDNA rather than the corresponding genomic DNA sequence with its introns, has multiple copies integrated in the same site, and when a bacterial gene is used (Houdebine, pg. 150 col. 2 lines 4-9). Overexpression of a transgene of interest also has inherent problems. This is often the case when the overproduced protein shares only a part of the properties of an endogenous

protein, which can result in inhibition of the endogenous protein, by the transgene of interest working in a transdominant negative manner (Houdebine, pg. 152, col. 2 parag. 4). The art continues that the generation of transgenic animals routinely involves one of two methods of exogenous DNA delivery to the recipient cells, retroviral infection or microinjection (Smith, pgs. 5-11). However, each method possesses significant unpredictability for the skilled artisan to implement. Retroviral vectors result in inconsistency and irreproducibility of transgene expression due to random integration with host DNA (Smith, pg. 6, col. 1 parag. 2), and instability due to the integrated retroviral DNA possessing the ability to spontaneously reactivate (Smith, pg. 6, col. 1 parag. 5). Microinjection of recipient cells with exogenous DNA presents the problem of mosaicism to the skilled artisan. The majority ($\approx$ 85%) of pronuclear microinjection-derived transgenic founders are mosaics of transgenic and non-transgenic cells (Smith, pg. 7, col. 2 parag. 2 lines 1-4). This becomes problematic since transmission of the transgene is dependent upon the existence and extent of germline colonization by transgene-containing cells, so that when transmission does occur, the transgene is inherited in a Mendelian fashion resulting in only a small portion of the transgene being passed onto offspring (Smith, pg. 7, col. 2 parag. 3, bridge pg. 8 col. 1 lines 1-8). In view of the art summarized above, the skilled artisan at the time of filing would surmise that the field of transgenesis is very unpredictable, and thus would require and undo amount of experimentation without a predictable degree of success to make and use the claimed transgenic rat animal.

It also important to note that the age and/or weight of the mice have not been disclosed by the specification. Since the injections of the vectors were done systemically via tail vein, it is assumed that the mice were at least born, at a minimum, and still not at the embryonic developmental stage. As stated above, the art teaches that transgenesis in animals other than mice is highly unpredictable. This applies also to the P-element vector system, even though the

transgenic mice created by the claimed method were already delivered (i.e. not in the womb). The difficulty and unpredictability in producing rat transgenic species involves significant inventive steps that each adds a level of unpredictability and would place an undue burden of experimentation by a skilled artisan to determine the specific heterologous promoter, and a single transcrtiptionally active gene that comprises said exogenous nucleic acid, wherein said single transcriptionally active gene is separated by one of said P-element trnasposase recognized insertion sequences by a distance of about 1,000 bp or less so that exogenous nucleic acid is inserted into said genome to produce rat transgenic animal other than mouse.

Therefore, in view of the lack of guidance provided by the specification as well as the unpredictability of the art, the claimed invention is not enabled for its full breadth and limiting the scope of the claimed invention to a method of inserting an exogenous nucleic acid into the genome of a mouse or a rat, wherein said method comprises introducing into said mouse a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is less than 1000 bp proximity to one of the P-element transposase recognized sequences and a transposase domain, <u>and</u> a method of inserting an exogenous nucleic acid into the genome of a mouse, wherein said method comprises introducing into said mouse a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is less than 1000 bp proximity to one of the P-element transposase recognized sequences, wherein said method further comprises inserting a second P-element vector comprising a transposase domain, and cells from said mouse or rat is proper.

Applicants argue have amended the claims to specify that the claimed method is performed in a mouse. However, Applicants have also included the rat embodiment in this amendment, based on the disclosure in the Specification at page 19, lines 18-22, wherein it is

set forth that male mice and rats were injected into their testis and these animals gave transgenic offspring. Applicants maintain that the present application provides sufficient disclosure to enable the invention to the full scope of the pending claims with regard to mice and rats. Once transgenesis is demonstrated in one rodent species (mouse) using the P-element derived vectors from such a divergent and unrelated species (Drosophila fly of phylum Arthropoda), it is reasonable to conclude that the methods can be extrapolatedto other rodents in a similar manner without undue experimentation. Rats are genetically and morphologically nearly identical to the mouse. Therefore, once the Applicants demonstrated the possibility of the described method with one species of rodent, it is reasonable to conclude that such methods can be used to generate transgenic rodents of different species using a vector that comprises a transposase recognized insertion sequence and an exogenous nucleic acid with a reasonable amount of experimentation.

These arguments are not persuasive because Applicants have not disclosed a P-element vector that integrates into a mouse or rat genome, wherein said vector comprises a pair of P-element transposase recognized insertion sequences flanking a P-feet flanked domain of at least about 2000 bp in length wherein said P-feet flanked domain comprises a heterologous promoter and a single transcriptionally active gene that comprises said exogenous nucleic acid, wherein said single transcriptionally active gene is separated from one of said P-element transposase recognized insertion sequences by a distance of about 1,000 bp or less, so that said exogenous nucleic acid is inserted into said genome. As discussed above at the time of the instant invention the art teaches that creating a transgenic mouse or rat animal, via a P-element transposition in the field of transgenesis is unpredictable. **Castro et al** et al note the molecular mechanisms that control P element transposition and determine its tissue specificity remain incompletely understood, although much information has been compiled about the

element in the last decade. **Plasterk et al,** note transgenic technology is currently applied to several animal species of agricultural or medical importance, such as fish, cattle, mosquitos and parasitic worms (abstract). However, the repertoire of genetic tools used for molecular analyses of mice and Drosophila is not always applicable to other species. For example, while retroviral enhancer-trap experiments in mice can be based on embryonic stem (ES) cell technology, this is not currently an option with other animals. Similarly, the germline transformation of Drosophila depends on the use of the P-element transposon, which does not jump in other genera. This article analyses the main characteristics of Tc1/mariner transposable elements, examines some of the factors that have contributed to their evolutionary success, and describes their potential, as well as their limitations, for transgenesis and insertional mutagenesis in diverse animals. The courts have stated that "tossing out the mere germ of an idea does not constitute enabling disclosure." Genentech, 108 F.3d at 1366 (quoting Brenner v. Manson, 383 U.S. 519, 536 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion")). "[R]easonable detail must be provided in order to enable members of the public to understand and carry out the invention." Id. In the instant case, such reasonable detail is lacking. The specification provides no guidance on how to use the compounds of claim 37 as beta-cell growth factors. 15. See Rasmusson v. SmithKline Beecham Corp., 75 USPQ2d 1297 (CA FC 2005) which teaches: "If mere plausibility were thetest for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11, 13-15, 27, 31 rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 13-15, 18, 27, 30-31 and 34 of the co-pending application 10/659,802 is withdrawn. A terminal disclaimer in compliance with 37 C.F.R. § 3.73(b) is filed on 3/3/08

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571) 272-3305. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Magdalene K. Sgagias, Ph.D.
Art Unit 1632

/Anne-Marie Falk/
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